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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,011	10/25/1999	MICHAEL SIMONS	BIS-043/CIP	1306
7590 07/13/2004				
DAVID PRASHKER PC P O BOX 5387 MAGNOLIA, MA 01930		EXAMINER TELLER, ROY R		
		ART UNIT PAPER NUMBER		
		1654		

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/426,011

Applicant(s)

SIMONS ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This office action is in response to the Request for Continued Examination (RCE), filed 3/30/04. Applicant's response has been fully considered.

Claims 11 and 12 have been amended.

Claims 11 and 12 are pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:7; peptide PR-11( experiment # 6, page 46 of the instant specification); who individually causes a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, does not reasonably provide enablement for a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide less than 26 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-

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Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro\_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. In view of the above, those skilled in the art are unlikely to accept the data as being correlatable to SEQ ID NO:3, a 15 amino acid residue and a family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one indentifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide less than 26 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro\_pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. Therefore, others skilled in the art would be unable to practice the invention as claimed without undue experimentation and with a reasonable expectation of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 12 recite "A family of PR-39 derived oligopeptides..." This is indefinite as to the metes and bounds of the oligopeptide/invention the applicant is claiming. Applicant is claiming an entire family of PR-39 derived oligopeptides whose members individually cause a selective inhibition of proteasome-mediated degradation for at least one identifiable peptide in-situ after introduction intracellularly to a viable cell, each member of said PR-39 derived oligopeptide family: being a peptide less than 26 amino acids residues in length; having a N-terminal amino acid residue sequence which begins with Arg-Arg-Arg; being a peptide which is devoid of the amino acid residue sequences Pro-Pro-X-X-Pro-Pro-X-X-Pro and Pro-Pro-X-X-X-Pro-pro-X-X-Pro where X is any amino acid; being able to interact in-situ with such proteasomes as are present within the cytoplasm of the cell; and being able to alter markedly the proteolytic degradation of at least one identifiable peptide mediated by said interacting proteasomes such that an increased expression of said identifiable peptide occurs in-situ. Applicant claim of a peptide of less than 26 amino acid residues in length does not adequately define the metes and bounds of the invention, as the invention(s) can be from about 8 to about 25 amino acids in length. This group of similar or related things is indefinite for not distinctly pointing out the claimed invention.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-12 are provisionally rejected under the judicially created doctrine of double patenting over claims 11-12 of copending Application No. 09/276,868.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11-12 in the instant application disclose a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acids residues and having an N-terminal sequence of Arg-Arg-Arg. SEQ ID NO: 3 is a 15 amino acid sequence. Thus, claims 11 and 12 in the instant application and claims 11 and 12 of the '868 application are obvious variants of a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acids residues and having an N-terminal sequence of Arg-Arg-Arg.

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This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross (USPN 6,133,233).

The instant invention is drawn to disclose a PR-39 derived oligopeptide family whose members individually cause a selective inhibition of proteasome-mediated degradation in-situ after introduction to a viable cell, and each member being an oligopeptide having less than 26 amino acids residues and having an N-terminal sequence of Arg-Arg-Arg. The instant invention provides an in-situ stimulation of angiogenesis. By definition, therefore, both in-vivo and in-vitro circumstances of use and applications are envisioned and expected (see, e.g., for example page 8)

Ross teaches an in vivo method of reducing reperfusion injury in a mammal which comprise the steps of administering into the mammal's bloodstream an effective amount of proline/arginine rich peptide. Ross discloses SEQ ID NO:4, a 14 amino acid peptide which is a

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92% query match with SEQ ID NO:3 of the instant application (see, e.g., for example, abstract, column 2, column 9, and claim 2).

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR



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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT

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7/9/04

RT

A handwritten signature in black ink, appearing to be 'C. R. Tate', written in a cursive style.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER